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10/598,432	08/30/2006	Jean-Luc Carrez	MART0910US	4952
24235 7550 08/27/2008 LEVINE & MANDELBAUM 444 MADISON AVENUE			EXAMINER	
			PATEL, SHEFALI DILIP	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/598,432 CARREZ ET AL. Office Action Summary Examiner Art Unit SHEFALI D. PATEL 3767 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 August 2006 and 06 November 2006. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-4.6-8.10-13.15-17.19 and 20 is/are rejected. 7) Claim(s) 5.9.14 and 18 is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 30 August 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

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DETAILED ACTION

Priority

 Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: FR 0402121, filed in France on March 2, 2005.

Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use, the specification has been submitted without any section headings:

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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(I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) <u>Title of the Invention</u>: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) <u>Statement Regarding Federally Sponsored Research and Development</u>: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc; The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(e)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000
- (f) <u>Background of the Invention</u>: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts;
 - Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

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- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) <u>Detailed Description of the Invention:</u> See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(c).

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(I) <u>Sequence Listing</u>, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Objections

3. Claim 1, 2, 4, 6, and 8 are objected to because of the following informalities:

In regards to claim 1 (page 2, lines 9-10), the limitation "where this **chamber** forms a chamber" should be corrected as "where this **cage** forms a chamber" based on the specification (page 7, line 3) in which it is disclosed that "the cage forms a chamber".

In regards to claims 2 (page 3, line 8), 6 (page 4, line 5), 8 (page 4, lines 17-18), 15 (page 6, line 4), and 17 (page 6, line 14), the term "the retention device" has not been introduced in previous claim 1. It is the Examiner's understanding that "the retention device" is the same as "a mobile device", which was introduced in claim 1. The same term should be used in all of the claims in order to avoid confusion.

In regards to claims 4 (page 3, line 17) and 13 (page 5, line 17), the limitation "the 10 lifting" should be corrected as "the lifting".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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 Claims 1-4, 11-13, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon (US 5,279,591).

In regards to claim 1, Simon teaches an arrangement (Figures 1-5, needle-catheter assembly [10]) for the insertion, into a vein, of a cannula composed of a short catheter (catheter [13]) with a proximal base (hub portion [22]), where this arrangement [10] includes:

- a needle (needle [12]) which has a puncture end (cutting end [15]) and a cage
 (guard protector housing [40]) which extends the base [22] of the cannula in the proximal direction (Figure 1)
- b. where this cage [40] forms a chamber (hollow body portion [52]) through which the needle [12] slides from a proximal entrance (rearward opening [53]) to a distal exit (forward end opening, not referenced) (Figure 1), and is equipped with a trap to hold the puncture end [15] of the needle [12] in the chamber [52] when the needle [12] is withdrawn from the catheter base [22] (Figure 2)
- c. with the cage [40] and the base [22] being equipped with retention resources that combine so as to perform temporary retention of the cage on the base before the puncture end [15] of the needle [12] is trapped in the chamber [52] of the cage [40] (Figure 1), with the said retention resources including an external rim (radially extending ears [27]) formed on the base [22], and an external dog (notches [50]) provided on the cage [40] to be held by this rim [27] (Figure 1) (column 7, lines 32-34)
- d. characterized in that the dog [50] is formed on a mobile device which includes a
 wall (sidewall segment [64]) traversed by a hole (between forward needle support [56]

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and longitudinally extending portion [65]) for the passage of the needle [12] so that the passage of the needle [12] in the hole holds the dog [50] in a retention position (Figure 1) e. the said wall [64] being mounted to slide in the chamber of the cage in a direction that is transverse to the needle [12], between a down held position (Figure 1) and an up released position (Figure 2), so that when the needle [12] is withdrawn into the cage [40] until it has moved to the rear of the said hole, the wall [64] which is not traversed by the needle [12] can slide to its up position (Figure 2), lifting the said dog [50] and allowing

In regards to claim 2, Simon teaches that said dog [50] is formed at the end of a wall (inner surface [47]) of the retention device which is at right angles to the sliding wall [64] (Figures 1-2).

the cage [40] to separate from the catheter base [22] (Figure 2)

In regards to claims 3 and 12, Simon teaches that said dog comprises a ramp (notches [50]) so that a reverse movement of the cage [40] in the proximal direction causes the dog to lift when the needle [12] no longer traverses said hole (Figure 2).

In regards to claims 4 and 13, Simon teaches that the arrangement [10] includes resources (forward needle support [56] and rearward surface [69]) in order to limit the lifting of the sliding wall [64] in the up position (Figure 2).

In regards to claims 11 and 20, Simon teaches that the arrangement [10] includes resources (inner surface [74] and friction material [59]) to prevent the point of the needle [12] exiting via the entrance [531 of the chamber [521 (column 10, lines 34-50).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 6, 8, 10, 15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, as applied to claims 1 and 2 above, and further in view of Ferguson et al (US 6,796,962).

In regards to claims 6 and 15, Simon teaches that the cage [40] is formed of a rear part which constitutes the chamber [52] and a front part which includes a transverse wall (radially-inwardly extending surface [48]) which closes off the said chamber [52] and which includes the exit from the chamber (Figure 3) (column 7, lines 17-19), this transverse wall [48] forming a slide for the sliding wall [64] of the said retention device (Figure 1 to Figure 2). Simon does not teach that the rear part and the front part are held together by a clock on action of nipples provided on the sides of the transverse wall of the front part, in holes formed in the wall of the chamber of the rear part, or vice versa, since Simon appears to teach that the rear part and the front part of the cage are a one-piece, integral structure (Figure 3). Ferguson et al teaches an arrangement (Figures 1-2) in which a cage (shield [300] with housing [312]) comprises a front part (housing first section [328]) and a rear part (housing second section [330]); said front part [328] and said rear part [330] are held together by nipples/holes (ribs, ridges, etc.) (column 6, lines 66-67 to column 7, lines 1-12). It would have been obvious to a person having ordinary

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skill in the art at the time the invention was made to modify the front part and the rear part, of the arrangement of Simon, with nipples/holes, as taught by Ferguson et al, as an obvious alternate structural design choice to the user, for a means to join the front part and the rear part of the cage together, in the case that the front part and the rear part are separable parts. Also, it has been held that constructing a formerly integral structure, as shown by Simon, in various elements (separable front part and rear part) involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179.

In regards to claims 8 and 17, in a modified arrangement of Simon and Ferguson et al,

Simon teaches that said transverse wall [48] of the front part of the cage [40] includes a nipple

(forward needle support [56]) which slides in an oblong aperture (rearward surface [69]) of the

sliding wall [64] of the retention device in order to limit the lifting of the mobile device (Figure 1

to Figure 2).

In regards to claims 10 and 19, in a modified arrangement of Simon and Ferguson et al, Simon teaches that the rear part of the cage [40] is shaped so that the base [22] of the needle [12] slots into the rear part for the puncture operation (Figure 1).

 Claims 7 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Simon and Ferguson et al, as applied to claims 6 and 15 above, and further in view of Greene et al (US 6.221,047). In regards to claims 7 and 16, in a modified arrangement of Simon and Ferguson et al, Simon does not teach that the front part of the cage [40] constitutes a nose designed to fit into the catheter base [22], since Simon appears to teach that the front part of the cage [40] fits around, and not into, the catheter base [22] (Figure 1). Greene teaches an arrangement [10] (Figures 1-10) in which the front part of a cage (needle cover [22]) constitutes a nose (first end [24]) designed to fit into the axial bore [20] of a catheter base (catheter hub [18]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the front part of the cage, of the modified arrangement of Simon and Ferguson et al, with a nose that fits into a catheter base, as taught by Greene et al, as an obvious alternate structural design choice to the user, for a means to join the cage with the catheter base; since regardless of whether the cage surrounds the catheter base in a connection, as taught by Simon, or the cage fits within the catheter base in a connection, as taught by Greene et al, the cage will be in a position to shield the puncture end of the needle when the needle is withdrawn from the catheter.

Allowable Subject Matter

9. Claims 5, 9, 14, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In regards to claims 5, 9, 14, and 18, the prior art of record does not disclose or render obvious at the time the invention was made the combination as claimed specifically including resources (such as flexible and elastic lateral legs) to prevent the mobile device returning to the down position after it has reached the up position.

Conclusion

 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Botich et al (US 6,077,244), Shue et al (US 7,044,935), and Ferguson et al (US 7,008,402)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Shefali D Patel/ Examiner, Art Unit 3767 | 08/21/2008 /Kevin C. Sirmons/ Supervisory Patent Examiner, Art Unit 3767